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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,852	09/05/2003	Neville Alleyne	ALLEYN2.001A	7244
20995	7590	05/22/2007	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			HOFFMAN, MARY C	
2040 MAIN STREET				
FOURTEENTH FLOOR			ART UNIT	PAPER NUMBER
IRVINE, CA 92614			3733	
			NOTIFICATION DATE	DELIVERY MODE
			05/22/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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SP

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/655,852	ALLEYNE, NEVILLE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary Hoffman	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 February 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 6-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 6-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (U.S. Patent No. 6,592,623) in view of Trieu (U.S. Patent No. 6,733,531)

Cauthen discloses a method of surgery, the method comprising: resecting a posterior lateral herniation in a spinal disk annulus; forming an opening in the annulus in a posterior lateral location (Column 2, lines 29-57); sealing the opening with a biocompatible seal wherein the seal is positioned to cover the opening (FIGS. 7A-8B, 12B); wherein sealing the opening includes positioning a protruding portion of the seal into the opening (FIG. 8B).

Cauthen discloses the claimed invention except for introducing a bone morphogenic protein into the opening.

Trieu discloses introducing pharmacological agents, such as bone morphogenic protein, into the hydrogel that is then positioned in the annulus in order to repair the annulus fibrosis and nucleus pulposus (col. 15, lines 4-6, lines 49-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Cauthen with the step of introducing bone

morphogenic protein into the annulus in view of Trieu in order to repair the annulus fibrosis and nucleus pulposus.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (U.S. Patent No. 6,592,623) in view of Trieu (U.S. Patent No. 6,733,531) as applied to claims 6-11 above, and further in view of Alleyne (U.S. Patent No. 5,437,672).

Cauthen, as modified, discloses the claimed invention except for the device being prepared in a color different than the viscera and skeletal tissue.

Alleyne discloses that surgical devices may be provided in contrasting colors to differentiate them from the surrounding tissue.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Cauthen, as modified in view of Trieu, with a contrasting color in view of Alleyne, in order to differentiate the device from the surrounding tissue.

### ***Response to Arguments***

Applicant's arguments filed 02/26/2007 have been fully considered but they are not persuasive.

Applicant argues that the patch of Cauthen is not combinable with the implant/reinforcing band of Trieu since Cauthen is directed to helping prevent the expulsion of the disk nucleus through the annulus, and the Trieu reference is directed toward replacing the disk nucleus. The examiner respectfully disagrees. The Cauthen reference explicitly states that the stent ref. #10 for sealing the annulus (the

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biocompatible seal of claim 1) is used when it is required to remove all or part of the intervertebral disc nucleus and a hydrogel is injected into the internal cavity of the flexible bladder implant. The Trieu reference states that it is known to introduce pharmacological agents, such as bone morphogenic protein, into hydrogel. Therefore, it would have been obvious to one of ordinary skill in the art that the time the invention was made to combine the two references to arrive at the method of claim 1. Moreover, Cauthen states in col. 7, lines 1-4 that the hydrogel is made from natural polymers, and it is well known in the art that natural polymers may contain BMP and other naturally occurring growth factors/proteins.

The rejections are deemed proper.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

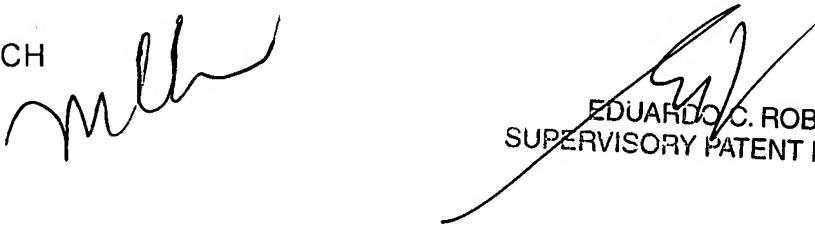
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER